

Foldable versus rigid intraocular lenses in phacoemulsification cataract surgery in Nepal

Submission date 29/10/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/02/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/02/2011	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Randomised controlled trial comparing the effectiveness and cost of foldable and rigid intraocular lenses in phacoemulsification cataract surgery in Nepal

Study objectives

The main aim of the trial is to compare the outcome of foldable and rigid intraocular lenses (IOLs) in phacoemulsification cataract surgery.

There is no significant difference in the visual outcome of phacoemulsification using either a rigid polymethylacrylate posterior chamber intraocular lens (PMMA PC IOL) or a foldable PC IOL.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. London School of Hygiene and Tropical Medicine (LSHTM) approved on the 22nd July 2010 (ref: 5714)
2. Nepal Netra Jyoti Sangh (NNJS), Institutional Research Review Board, Kathmandu/NEPAL, approved on the 27th August 2010 (ref: 52-067-068)

Primary study design

Interventional

Study design

Randomised interventional single-centre study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cataract surgery (phacoemulsification)

Interventions

In both treatment groups, the cataract will be removed by phacoemulsification, using phaco chop technique (phaco machines: OS-3 OERTLI, Megatron GEUDER). The remaining cortex will be removed with Simcoe cannula and/or bimanual irrigation/aspiration system. In the "foldable" group, the intraocular lens (hydrophilic acrylic, IOCare, India) will be inserted with an injector through the 2.5 mm corneal incision and placed in the capsular bag. In the "rigid" group, the sclero-corneal incision will be enlarged to 5 mm and a 5 mm optic PMMA IOL (IOCare, India) will be inserted into the capsular bag. The surgery will be performed by two surgeons, both of whom are experienced in using both types of lenses. Treatment is a one-off procedure; follow-up is 12 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Visual acuity at one year after surgery in the operated eye:

1. Uncorrected visual acuity of 6/9 or more (i.e. very good functional vision)
2. Uncorrected visual acuity of 6/18 or more (i.e. operated eye is no longer "visually impaired" by World Health Organization [WHO] definitions)
3. Best corrected visual acuity worse than 6/60 (i.e. eye is effectively blind)

Key secondary outcome(s)

1. Visual acuity in the operated eye at other time points
2. Complications during surgery
3. Early post-operative complications
4. Long term complications
5. Astigmatism
6. Cost

Measured at 6 weeks and 12 months.

Completion date

24/09/2012

Eligibility

Key inclusion criteria

Patients with cataract, aged 35 to 70 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Corneal endothelial disease (Fuchs' dystrophy; corneal stromal scarring)
2. Intraocular pressure greater than 22 mmHg
3. A-Scan finding: less than 17.0 dpt, greater than 26.0 dpt
4. Any other eye disease except age related cataract
5. Very advanced hard lens nuclei, where phaco is not suitable (grade III+)
6. Diabetes mellitus

Date of first enrolment

25/09/2010

Date of final enrolment

24/09/2012

Locations

Countries of recruitment

Nepal

Study participating centre
Sagarmatha Choudhary Eye Hospital
Lahan
Nepal
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Sponsor information

Organisation
Sagarmatha Choudhary Eye Hospital (Nepal)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sagarmatha Choudhary Eye Hospital (Nepal)

Funder Name
CBM eV (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration